DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 22, 2015

Catheter Connections, Inc.
Mr. Mark Endo
Director Quality Assurance
2455 East Parleys Way, Suite 150
Salt Lake City, UT 84109

Re: K142806
Trade/Device Name: DualCap® Disinfectant Caps
Regulation Number: Unclassified
Regulation Name: Pad, Alcohol, Device Disinfectant
Regulatory Class: Unclassified
Product Code: LKB
Dated: April 17, 2015
Received: April 20, 2015

Dear Mr. Endo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142806

Device Name

DualCap® Disinfectant Caps

Indications for Use *(Describe)*

When left in place for 30 seconds the Light Blue DualCap® disinfects needleless luer access valves and the Dark Blue DualCap® disinfects the IV administration line male luer connections; thereafter the caps provide a physical barrier to contamination up to 7 days, under normal conditions if not removed.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K142806

510(k) SUMMARY

(21 CFR 807.92)
for the Catheter Connections' DualCap® Disinfectant Caps

SUBMITTER:

Catheter Connections, Inc.
2455 East Parley's Way, Suite 150
Salt Lake City, UT 84109

CONTACT PERSON:

Mark Endo
Telephone: (801) 906-0820
Fax: (888) 862-2693
Email: mendo@cathconn.com

DATE PREPARED: May 22, 2015

SUBMISSION DEVICE:

Trade/Device Name:	DualCap® Disinfectant Caps
Regulation Number:	Unclassified
Regulation Classification Name:	Pad, Alcohol, Device Disinfectant
Regulatory Class:	Unclassified
Classification Product Code:	LKB
Classification Advisory Panel:	General Hospital

PREDICATE DEVICE:

Catheter Connections' DualCap® (K093229):
(This predicate device has not been subject to a design-related recall)
(No reference devices were used in this submission)

Trade/Device Name:	Catheter Connections' DualCap®
Regulation Number:	Unclassified
Regulation Classification Name:	Pad, Alcohol, Device Disinfectant
Regulatory Class:	Unclassified
Classification Product Code:	LKB
Classification Advisory Panel:	General Hospital

DEVICE DESCRIPTION:

The DualCap® Disinfectant Cap is designed to fit securely on Luer access valves and IV administration line male Luer connections. The cap contains 70% isopropyl alcohol. The Subject device is **not made with natural rubber latex**, is **non-pyrogenic**, **non-preservative** and **is not made with DEHP**. The product consists of a Light Blue DualCap® for use on Luer access valves and a Dark Blue DualCap® for use on IV administration line male Luer connections. The Light Blue DualCaps® and Dark Blue DualCaps® are available in a number of packaging combinations such as two Light Blue DualCaps®, a Light Blue DualCap® and Dark Blue DualCap® combination, and as singles.

Additionally, DualCap® Disinfectant Caps will be marketed for use as an accessory in procedure kits. When being used in procedural kits, the product will be shipped bulk to the kitting manufacturer.

INTENDED USE:

The DualCap® Disinfectant Caps are intended for use on luer access valves and the IV administration line male Luer connections. DualCap® Disinfectant Caps will disinfect and decontaminate the valve and male luer and act as a barrier to contamination between IV administration line accesses.

INDICATIONS FOR USE:

When left in place for 30 seconds the Light Blue DualCap® disinfects needleless luer access valves and the Dark Blue DualCap® disinfects the IV administration line male luer connections; thereafter the caps provide a physical barrier to contamination up to 7 days, under normal conditions if not removed.

The Indications for Use statement for DualCap® Disinfectant Caps is not identical to the predicate device; however, the differences do not alter the intended use of the subject device nor do they affect the performance of the device relative to the predicate. Both the subject device and predicate device have the same intended use.

COMPARISON OF PREDICATE DEVICE IFU STATEMENT AND SUBECT DEVICE IFU STATEMENT

Predicate Device IFU Statement	When left in place for 5 minutes the female component of DualCap™ disinfects needleless luer access valves and the male cap of DualCap™ disinfects IV line male luer connectors; thereafter the caps provide a physical barrier to contamination up to 96 hours under normal conditions if not removed.

Subject Device IFU Statement	When left in place for ~~5 minutes~~ 30 seconds the ~~female component of~~ Light Blue DualCap™ disinfects needleless luer access valves and the ~~male cap of~~ Dark Blue DualCap™ disinfects IV line male luer ~~connectors~~ connections; thereafter the caps provide a physical barrier to contamination up to ~~96 hours~~ 7 days under normal conditions if not removed.

There are two major differences in the predicate device IFU and the subject device IFU

1.) There is a decreased minimum exposure time, going from 5 minutes to 30 second disinfection time for luer access valves and IV line male luer connections using the DualCap® Disinfectant Caps.

2.) There is an increase in time going from 96 hours to 7 days, in which the DualCap® Disinfectant Caps can be left in place, providing a physical barrier.

These changes in time for disinfection and providing a physical barrier to contamination, do not affect the performance of the DualCap® Disinfectant Caps because there has been no change in the design of the predicate device and subject device as described below.

To support the change in disinfection time indicated above, *In-vitro* antimicrobial efficacy studies were completed on the DualCap® Disinfectant Caps to support the 30 second 30 day disinfection time.

To support the change to the seven (7) day use of life claim, testing was performed to show that there was an air tight seal between the LAV and light blue DualCap® Disinfecting Cap and an air tight seal between the male luer connector and the dark blue DualCap® Disinfecting Cap, after 7 days.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

Disinfection of surfaces by exposure to 70% isopropyl alcohol (IPA) contained in a plastic cap while protecting the fluid pathway from disinfectant contamination is the general principle for both the subject device and predicate devices. The subject device and predicate devices are both based on the following technological elements:

- The DualCap® Disinfectant Caps contains both a disinfecting cap for luer access valves and male luer connectors
- They utilize an IPA reservoir
- They utilize an elastomeric tip to block the fluid pathway upon connection to a male luer
- They are mechanically secured via ISO compliant threads onto male luer connectors
- They disinfect and protect both luer access valves and male luer connectors
- The devices are radiation sterilized

There are no technological differences between the subject device and the predicate device:

- The subject device is physically identical to the predicates device. They have the same technological characteristics:
    - Same design
    - Same materials
    - Same components
    - Same method of manufacture
    - Same plastic injection molds used to make the polypropylene Light Blue caps and Dark Blue caps
    - Same method of operation
    - Same sterilization method
- No change in the function/performance indication
- No change in patient population
- No change in clinical context

PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the subject device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995. The subject device and predicate devices are identical. The battery of tests included the following:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Systemic Toxicity
- Hemocompatibility

Microbiological testing

In vitro antimicrobial efficacy studies were completed on the DualCap® Disinfectant Caps under worst case conditions and show a ≥ 4 log reduction in each test organism **(***Staphylococcus aureus*, *Staphylococcus epidermidis*, *Pseudomonas aeruginosa*, *Escherichia coli* and *Candida albicans*).

Other performance tests

Physical tests were performed to ensure that the DualCap® Disinfectant Caps were compatible with typical luer access valves and male luer devices such as those found on IV administration sets. Applicable testing using ISO 594 was completed. The DualCap® Disinfectant Caps passed all tests which include the following:

- Conformance to ISO 594 (ISO 594-1): 5.1 (Gauging) Dark Blue DualCap® for use on Male Luers
- Conformance to ISO 594 (ISO 594-1): 5.2 (Liquid Leakage Under Pressure) Dark Blue DualCap® for use on Male Luers
- Conformance to ISO 594 (ISO 594-1): 5.4 (Separation Force) Dark Blue DualCap® for use on Male Luers
- Conformance to ISO 594-2: 5.6 (Ease of Assembly) Dark Blue DualCap® for use on Male Luers is compatible with standard male Luer IV connectors
- Conformance to ISO 594-2: 5.7 (Resistance to Overriding) Dark Blue DualCap® for use on Male Luers is compatible with standard male luer IV connectors
- Confirmation of ISO 594-2 Compliant Securement Threads Applicable to both the Light Blue DualCap® for use on Luer Access Valves and the Dark Blue DualCap® for use on Male Luers
- Conformance to ISO 594-2: 5.6 (Ease of Assembly) Light Blue DualCap® female cap component is compatible with standard accessible injection valves
- Conformance to ISO 594-2: 5.7 (Resistance to Overriding) Light Blue DualCap® Disinfectant Cap component is compatible with standard accessible injection valves

Testing was also completed to demonstrate that the DualCap® Disinfectant Caps for Male Luers did not allow disinfectant to enter into the fluid path of the male luers.

- Verification that the Dark Blue component of DualCap® for use on Male Luers cap seals the male Luer connector and does not allow alcohol to enter into the male luer intraluminal space.

CONCLUSION

Based on the data provided in this submission, it can be concluded that the subject device is physically identical to the predicate device in terms of intended use (which is to disinfect and protect luer access valves and male luer connectors), design, materials, operation, function, and sterilization method. The performance bench tests completed in this submission demonstrate that the Subject device is substantially equivalent to the Predicate Device (K093229). The In-vitro Microbial Efficacy Studies and air tight seal study, also completed in this submission, support the change to a disinfection time of 30 seconds and the use of life (i.e. physical barrier to contamination) claim of 7days, for the DualCap® Disinfectant Caps.